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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
|---|---|---|---|
| 09/642,242 | 08/17/00 | ANDRYSEK T | UD&LP049 |

022434 HM12/1005
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| EXAMINER | |
|---|---|
| LUKTON, D | |
| ART UNIT | PAPER NUMBER |
| 1653 | 9 |

DATE MAILED: 10/05/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

| Application No. | Applicant(s) |
|---|---|
| 09/642,242 | Andrysek |
| **Examiner** | **Art Unit** |
| David Lukton | 1653 |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) ☒ Responsive to communication(s) filed on *Jul 30, 2001*

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

**Disposition of Claims**

4) ☒ Claim(s) *1-32* is/are pending in the applica

4a) Of the above, claim(s) *1, 3-24, 26, 28, 30, and 32* is/are withdrawn from considera

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *2, 25, 27, 29, and 31* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirem

**Application Papers**

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. § 119**

13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☒ All b) ☐ Some* c) ☐ None of:

1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

**Attachment(s)**

15) ☐ Notice of References Cited (PTO-892)

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 4

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☐ Other:

Applicants' election of Group II (claims 2, 25, 27, 29, 31) with traverse is acknowledged, as is the elected specie.

Applicants have argued that claim 30 should be joined with the elected group. The examiner would agree to the extent that in the event that claim 2 proves to be novel, novelty would likely accrue to claim 30 as well, barring any assertions to the contrary which might be made by applicants during the course of prosecution. Accordingly, in the event that the elected claims are determined to be allowable, it is likely to be the case that claim 30 would be rejoined therewith, provided that whatever limitations are agreed to for claim 2 would apply to claim 30 as well. Applicants have also argued that no additional burden would be sustained in examining the Group I claims. This may turn out to be true, and it may not. It depends on what is taught in the art, and what applicants are willing to stipulate. The restriction between Groups I and II is maintained at the present time; however, in the event that Group II claims prove to be allowable, it would be appropriate to revisit the matter of restriction between Groups I and II.

The restriction is maintained at the present time.

*

The following is a quotation of the first paragraph of 35 U.S.C. §112:

The specification shall contain a written description of the invention, and of the manner and process of making

and using it in such full, clear, concise and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2, 25, 27, 29, 31 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 2 is drawn to a "pharmaceutical formulation". The term "pharmaceutical" implies therapeutic efficacy, which is not in evidence.

In example 8, applicants have asserted that they have provided a "verification of biovailabiltiy". However, this assay employed the composition of example 1; the composition of example 1, in turn, contains alcohols, which is a non-elected invention. Accordingly, example 8 does not contribute to the enablement. In addition, a "non-specific immunoassay" was used to assess cyclosporin levels. However, an immunoassay does not necessarily distinguish between hydrolyzed and non-hydrolyzed peptide; moreover, even if it is possible to increase the concentration of a given composition (containing an active agent) in blood, it is not necessarily the case that the active agent in question is more bioavailable. If it is indeed true that at a time point two hours after administration, the concentration of the composition containing cyclosporin is in fact higher than if "Neoral" was used, that does not prove that the cyclosporin will be more bioavailable to the tissues that would benefit from it. The

claimed composition may affect the ability of the cyclosporin to distribute from the blood into various tissues. Thus, this experiment does not establish a therapeutic efficacy of the composition containing cyclosporin.

On p. 22 a "bioequivalence study design" is described, but the compositions used are not set forth. The assumption is at this point that the claimed composition was not used.

Given that applicants have not established therapeutic efficacy for any of the claimed compositions, it is suggested that the term "pharmaceutical" be deleted from line 1 of claim 2.

In addition to the foregoing, claim 2 recites the term "effective amount". However, it is not the case that the active ingredients are effective for anything and everything. For example, it is not the case that the active ingredients are effective for curing Alzheimer's Disease, or for treating AIDS or for making people thinner or smarter. If applicants are going to use the term "effective amount", the objective of the efficacy should be both specified and enabled.

*

Claims 2, 25, 27, 29, 31 are rejected under 35 U.S.C. §112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- Claim 2 is indefinite as to the objectives of the "effective amount".
- In claim 2, line 4, the term "selected" is misspelled.

- In claim 2, formula (2) is provided. Within this formula is an uppercase "N". However, only a lowercase "n" is defined.

- In each of claims 25 and 27, the word "especially" appears in line 2. This word is superfluous should be eliminated.

- In claim 29, the term "substance" is used. This term is intended to refer to compounds, not unidentified materials. Accordingly, the term *compound* should be used, as it is more exact.

- Claim 31, line 2 contains an obvious grammatical error.

Reference "M" was stricken from the IDS because of the absence of a translation.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton. Phone: (703) 308-3213.

An inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

DAVID LUKTON
PATENT EXAMINER
GROUP 1800